**National Cancer Institute (NCI) Central IRB (CIRB) Local Management Process and Guidance**

This guidance describes the procedures local investigators/research team members must follow to comply with local institutional oversight requirements for studies under the purview of the NCI CIRB.

**Initial Submission of an NCI CIRB Study**

1. Check NCI CIRB website to ensure the project has NCI CIRB approval and is Group activated.
2. Submit a *Study-Specific Worksheet* to the NCI CIRB to obtain approval to conduct the study at LSUHSC or affiliates.
3. Complete and submit the *Reliance Request* protocol in the Kuali Research (KR) electronic submission system. Include the letter of approval from the CIRB to conduct the study at LSUHSC. Instructions for accessing KR and preparing the *Reliance Request* protocol are available [here](https://www.lsuhsc.edu/administration/academic/ors/kuali_quickguides.aspx).
4. Once all local requirements have been verified, including training compliance, HIPAA waiver (if applicable), and ancillary committee review (if applicable), the HRPP will issue approval of the reliance request protocol to the Principal Investigator.
5. Initiate the study only when HRPP has approved the reliance request **AND** the NCI CIRB has approved the local site and PI for the study.

**Post-Approval Study Requirements**

1. After your study is approved, CIRB will be the IRB of record for the life of the study. All communication regarding the study will be between the Investigator and CIRB.
2. The PI (and/or designated contact) will work directly with CIRB on study modifications, continuing reviews, and reportable events. Submission of relevant forms do not need prior authorization by the LSUHSC HRPP.
3. The PI and study team are required to submit, in KR, select information to the HRPP on an on-going basis as follows:
	1. **Study Modifications (including change in personnel):** Use the *Amendment* form linked to the approved *Reliance Request* protocol to submit all modifications to the study. Under most circumstances, this will entail only submission of the letter of approval from the CIRB for the study modification.
	2. **Continuing Review:** Submit the Continuing Review letter of approval from the CIRB using the *Renewal* form linked to the approved protocol in KR.
	3. **Reportable Events:** Submit the letter of acknowledgment from the CIRB using the *Reportable Event* form linked to the approved protocol in KR. If the event occurred at LSUHSC (or an associated performance site), submit the event only if it rises to the level of an [Unanticipated Problem](https://www.lsuhsc.edu/administration/academic/ors/unanticipated_problem.aspx). If the incidence did not occur locally, report the event only if required by the CIRB.
	4. **Study Closure:** Submit the Study Closure letter of approval from the CIRB using the *Close Request* form linked to the approved protocol in KR.

**LSUHSC’s HRPP External IRB Relations Liaison**

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